UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,670	05/07/2002	Audrey Goddard	P3230R1C001-168	7260

30313 7590 10/20/2005

KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 MAIN STREET
IRVINE, CA 92614

EXAMINER	
NICKOL, GARY B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,670	GODDARD ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-13 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-13 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Re: Goddard *et al.*

Date of priority: 10/29/1997

Request for Continued Examination

The request filed on 08-05-2005 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/063510 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 5-13, 17-20 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 5-13, 17-20 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons of record as set forth in the Actions mailed 09-13-2004 and 05-04-2005 and as further set forth below.

Applicant's arguments (Response, page 4) are accompanied by a Declaration under 37 C.F.R. 1.132 from one of the inventors, Dr. Paul Godowski.

Parts 1-3 of the declaration merely describe the experimental procedures used to measure TNF-α release from human blood in-vitro and therefore do not constitute any substantial arguments that particularly address the utility of the claimed invention.

Part 4 of the declaration argues that the assay was conducted using well-accepted and established scientific procedures and that the results reported in Example 17 are reliable and reproducible. This argument has been considered but is not found relevant. While the results may be reproducible and or reliable, such arguments do not address a substantial or specific utility regarding TNF-α release from the blood. Dr. Godowski argues that PRO polypeptides reported as positive in the assay stimulated the release of at least 50-fold and up to more than 300-fold more TNF-α than the control samples. In contrast, Dr. Godowski notes that TNF-α is normally undetectable in human blood. Again, however, such statements regarding release of TNF-α fail to ascribe a real world utility or substantial use for increasing TNF-α in blood. Thus, the statements in Part 4 are not found persuasive.

In Part 5 of the declaration, Applicants appear to be rebutting the Examiner's discussion of the Goeddel reference (Action mailed 05-04-2005, page 4), which was first submitted by Dr. Godowski in his Declaration filed 12-14-2004 (see page 2, 1st paragraph). Presently, Dr. Godowski argues that one cannot extend the transient induction of TNF-α production by murine macrophage cells upon contact with PMA to infer that the *claimed* polypeptides will necessarily induce transient production of TNF-α in human cells. While the latter may be true, applicant's arguments do not address why any general increase in TNF-α in human blood would be of substantial utility, especially in view of the fact that that Goeddel *et al.* teaches (page 602) that increases in TNF-α can

both inhibit the growth of cells and or stimulate the growth of cells. Applicants merely maintain (Response, page 5) that the utility requirement only mandates that the claimed polypeptide have beneficial activity with respect to at least one cell type. This argument has been considered but is not found persuasive because the utility requirements are not limited to such narrow guidelines. The question of utility is always made on a case-by-case basis taking into consideration the nature of the invention, the teachings of the prior art as well as the entire disclosure.

Dr. Godowski also argues that the in vitro assays of the Goeddel reference are not comparable to in vivo therapy. This argument has been considered but is not found persuasive as applicant's experimental conclusions also relied solely on the results from in vitro experiments. Accordingly, applicant's experiments would also not necessarily extrapolate to any proposed in vivo therapy.

Part 6 of the declaration assumes that the declaration has provided substantial evidence to support a real world utility to increasing TNF-α levels. However, the declaration never describes any benefit to increasing TNF-α levels to treat any specific condition. The declaration uses the latter to introduce the idea that *reducing* TNF-α may treat certain conditions. Applicants argue that inhibition of polypeptides that enhance TNF-α production, such as the claimed nucleic acids encoding the claimed PRO polypeptides, is useful for treating such conditions as Crohn's disease and rheumatoid arthritis. This argument has been considered but is speculative at best because there is no evidence to suggest that that the claimed PRO polypeptide is involved in stimulating TNF-α release under such conditions.

Applicants further argue (Response, page 6) that stimulation of TNF-α release meets the MPEP test--that a compound have "*mere identification of a pharmacological activity*". This argument has been considered but is not found persuasive because there is no specific or substantial nexus between the disclosed pharmacological activity and a real-world pharmacological use that provides an immediate benefit to the public. Thus, for the reasons of record and for the reasons set forth above, applicant's arguments and the declaration have not been found persuasive and the rejection is maintained.

Claims 5-13, 17-20 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to *use* the claimed invention for the reasons of record.

Claims 6, and 9-10 remain rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention for the reasons of record.

Applicants argue (Response, page 8) that Figure 6 discloses the presence of a transmembrane domain between amino acids 235-254 of SEQ ID NO:5. Applicants argue that the demarcation of these regions of the protein also demarcate the amino acids at positions 17-234 of the polypeptide of SEQ ID NO:6. This argument has been carefully considered but is not found persuasive. The disclosure, only, of a complete amino acid sequence does not provide a written description or evidence of contemplation for any specific regions within that sequence. The disclosure itself must have also contemplated

such regions. Thus, applicant's arguments have not been found persuasive, and the rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER